1155-99 **Similar Clinical Outcomes for Sirolimus-Eluting Stent Implantation and Coronary Brachytherapy for the Treatment of In-Stent Restenosis**

Francesco Saia, Pedro A. Lemos, Angela Hoye, Georgios Sianos, Chourmouzios A. Arampatzis, Willem J. van der Giessen, Pieter C. Smits, Ron T. van Domburg, Pim J. de Feyter, Patrick W. Serruys, Erasmus University Medical Center, Rotterdam, The Netherlands

Background: Preliminary studies have shown that sirolimus-eluting stent (SES) implantation is safe and effective for the treatment of in-stent restenosis (ISR). However, the clinical efficacy of this new therapeutic approach has not been compared to coronary brachytherapy (CBT), the best treatment currently available for ISR.
Methods: We assessed the incidence of major adverse cardiac events (MACE = death, myocardial infarction, target lesion revascularization) in 43 consecutive patients treated with CBT at our institution for ISR (CBT group) and 44 consecutive patients with ISR, without prior irradiation of the target vessel, treated with SES implantation (SES group).
Results: Baseline clinical characteristics of the two groups were similar. Relatively more ISR lesions per patient were treated in the SES group (1.2±0.5 versus 1.0±0.2; p=0.02). Angiographically, the prevalence of Mehran class I and II lesions was similar among the two groups (66% CBT versus 63% SES; p=0.7). In the CBT group periprocedural glycoprotein IIb/IIIa inhibitors utilization was more common (33% versus 9%; p=0.007), and clopidogrel prescription longer (7.5±5.5 months vs 5.9±2.6 months; p=0.005). During 9 months of follow-up, 3 patients (7%) died in the CBT group and 0 in the SES group. The incidence of myocardial infarction was 2.3% in both groups. Target lesion revascularization was performed in 11.6% of the CBT patients and 16.3% of the SES patients (p=ns). The 9-month MACE-free survival was similar in both groups (79.1% CBT versus 81.5% SES; p=0.8 by log rank).
Conclusions: This non-randomized study suggests that sirolimus-eluting stent implantation is as effective as vascular brachytherapy in the treatment of in-stent restenosis.

1155-100 **Intracoronary Radiation Therapy Using a Novel Beta Emitter for In-Stent Restenosis: Tungsten WRIST**

Ron Waksman, Andrew E. Ajani, Christian E. Dilcher, Janice K. Lavoie, Rebecca Torguson, Afework GebreEyesus, Rosanna C. Chan, Michael Porrazzo, Lowell F. Satler, William O. Suddath, Augusto D. Pichard, Kenneth M. Kent, Joseph Lindsay, Washington Hospital Center, Washington, DC

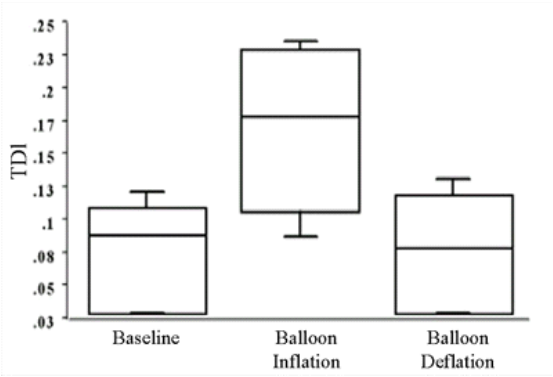
Background: Tungsten WRIST is a safety and feasibility study of intracoronary radiation therapy utilizing Tungsten (^{188}W), a beta emitter. In animal studies, ^{188}W has achieved effective reduction of neointimal proliferation with doses up to 25 Gy at 2mm.
Methods: Thirty patients (pts) with in-stent restenosis (ISR) of native coronary arteries were treated with PCI (balloon angioplasty, rotational atherectomy, laser ablation, or additional stenting) and intracoronary radiation with ^{188}W. The Tungsten source with an active length of 33mm (total length 40mm, diameter 1mm) was manually delivered over a guidewire. The prescription doses were 18 Gy (n=10), 22 Gy (n=10), and 25 Gy (n=10) at 2mm radial distance from the center of the source. All pts received lifelong aspirin and clopidogrel for at least 6 months.
Results: Pts were: male 67%, diabetics 43%; and age 58 ± 12 yrs. ISR lesions involved the LAD in 67% of the cases. Preprocedure reference vessel diameter was 2.69±0.46mm and lesion length was 16.09±6.91mm. In 7%, an additional stent was used. Balloon angioplasty alone was done in 47% of pts. In all pts radiation was successfully given with no procedural complications. All pts completed 6-month follow-up. There were no differences in angiographic restenosis.
Conclusions: Intracoronary delivery of the Tungsten source was feasible and safe. Doses of 18-25 Gy were associated with similar clinical events when compared with other beta and gamma emitters used in clinical practice for the treatment of ISR.

	18 Gy (N=10)	22 Gy (N=10)	25 Gy (N=10)	Total % (n=30)
Binary Restenosis %	11	12.5	10	11
Late Loss (mm)	0.43±0.78	-0.18±0.24	0.18±1.42	0.14±0.88
TLR	1 (10%)	1 (10%)	2 (20%)	4 (13%)
TVR	3 (30%)	1 (10%)	3 (30%)	7 (23%)

1155-101 **In Vivo Temperature Measurements of Human Atherosclerotic Plaques With a New Balloon-Thermography Catheter: The "Cooling Effect" of Blood Flow**

Eleftherios Tsiamis, Konstantinos Toutouzas, John Mitropoulos, Sophia Vaina, Manolis Vavuranakis, Costas Tsioufis, John Kallikazaros, Christos Pitsavos, Christodoulos Stefanadis, Hippokration Hospital, Athens, Greece

Background: Ex vivo and in vivo temperature measurements of the human atherosclerotic plaques present a mismatch. This may be due to the 'cooling effect' of blood flow. In order to test this hypothesis we designed a new balloon-thermogaphy catheter for temperature measurements during coronary flow interruption. **Method:** A thermistor probe is positioned at the distal segment of the catheter. Exactly opposite is placed a balloon. During balloon inflation coronary flow is progressively interrupted. We studied 10 patients with effort angina. Coronary flow velocity was continuously recorded. Temperature was recorded at the proximal vessel wall and at the lesion before, during and after complete interruption of blood flow. TDb was assigned as the difference between the background and the maximal temperature during and after balloon inflation. TDI was assigned as the difference between the atherosclerotic lesion and the proximal vessel wall. **Results**: TDb during and after balloon inflation was 0.01±0.01 and -0.003±-0.01°C (p<0.001) respectively. TDI was 0.07±0.04°C at baseline, 0.17±0.06°C (59.3±11.8% increase) during and 0.07±0.05°C after flow interruption (p<0.001)(Figure). TDI was greater than TDb during and after obstruction of flow (p<0.001). **Conclusions:** In vivo atherosclerotic plaque temperature recording with this new balloon-thermography catheter introduces a new method for the detection of thermal heterogeneity in plaques and possibly resolves the issue of 'cooling effect' of blood flow.



POSTER SESSION

1156

Carotid Stenting: Immediate and Late Outcomes

Tuesday, March 09, 2004, 3:00 p.m.-5:00 p.m.
Morial Convention Center, Hall G
Presentation Hour: 3:00 p.m.-4:00 p.m.

1156-59 **Comparison of Interventional Versus Conservative Treatment of Isolated Ostial Lesions of Coronary Diagonal Branch Vessels: Results of a Prospective Single Center Trial**

Martin Brueck, Martin Heidt, Wilfried Kramer, Josef Ludwig, Clinic of Wetzlar, Wetzlar, Germany, Justus-Liebig-University of Giessen, Giessen, Germany

Background. Percutaneous coronary intervention (PCI) of ostial stenosis of coronary artery side branches are associated with reduced success and increased complications. Therefore, it was the aim of the study to compare PCI with medical treatment of isolated ostial stenosis of diagonal branches for reducing the incidence of ischemic events.
Methods. The study group comprised 302 patients with ostial stenosis > 75 % of the diagonal branch and a vessel diameter ≥ 2 mm of the diagonal branch without further significant (< 50 %) coronary artery stenoses. The decision of medical or interventional treatment was left to the discretion of the operator. 233 patients (77 %) were treated medically (Group I), and 69 patients (23 %) underwent PCI (Group II). All patients went into a database looking for death, myocardial infarction, recatheterization or angina at 12 months either by clinical examination or telephone call.
Results. Successful dilation of the ostial branch stenosis was obtained in 65 of 69 patients of Group II (94 %). In-hospital clinical outcome (death, acute myocardial infarction, refractory angina) were not different between both strategies. At 12 months follow-up, 51 of 233 patients of Group I (22 %) were rehospitalized due to cardiac complaints compared to 38 of 59 patients (55 %) of Group II (p < 0.001). 45 patients of Group I (19 %) and 32 of Group II (46 %) underwent recatheterization (p < 0.001). In 19 patients of Group I (8 %) and 16 of Group II (23 %) (re-)PCI was necessary (p = 0.001). There were no significant differences concerning death and myocardial infarction between both groups after 12 months. Interventional treatment did not result in a higher incidence of freedom of angina (41 %) compared with medical treatment (56 %; p = 0.255).
Conclusion. Medical treatment of isolated ostial stenosis of diagonal branches is an alternative to percutaneous intervention without higher incidence of death or myocardial infarction at 12 months follow-up. Interestingly, patients with isolated ostial stenosis of diagonal branches treated by PCI showed a significantly higher probability of rehospitalization, recatheterization and re-PCI compared to medically treated patients.

1156-60 **Predilatation Before Distal Protection Device Placement in Stenting Carotid Arteries Is Successful and Not Associated With Adverse Outcome**

Giora Weisz, Jiri J. Vitek, Christina Brennan, Ian Dalagin, Gary Roubin, Sriram S. Iyer, Lenox Hill Heart and Vascular Institute of New York and Cardiovascular Research Foundation, New York, NY

Background: The use of distal protection devices (DPD) is gaining growing acceptance as standard therapy to prevent distal embolization during carotid artery stenting (CAS). It is optimal to have the device deployed during all phases of intervention, but this may not be possible in tight and complex lesions, in which device crossing may be difficult. We therefore examined whether the need for balloon pre-dilatation prior to lesion crossing

with the DPD impacts outcomes.
Methods: Between 2/2000 – 3/2003, 551 pts with carotid disease had 588 procedures of CAS. All clinical variables, technical details, and results were documented prospectively. Clinical outcomeswere prospectively monitored for 30 days post procedure.
Results: In 45 (7.7%) procedures the lesion was pre-dilated before DPD deployment, using 1.5-2mm diameter balloon. In 40 (89%) of them, the reminder of the procedure, including DPD and stent placements, were successful. One patient had a "string" sign, so no further intervention was attempted. In one patient DPD was successfully deployed, but the stent could not be placed due to severe proximal tortuousity. In 3 cases, a filter-based DPD could not cross the stenosis despite pre-dilatation. In 1 of them, distal balloon-based DPD and stent were successfully deployed. The other two had stenting without embolic protection. There were no strokes or mortality in the pre-dilatation group pts.
Conclusion: 1. Balloon pre-dilatation prior to DPD placement was needed in very tight and complex lesions, and enabled a DPD system to cross the lesion in 96% of these cases. 2. Balloon pre-dilatation prior to DPD placement was safe, and was not associated with any major adverse events.

1156-61 The Safety of Carotid and Cerebral Angiography Performed by Cardiologists in the Cardiac Catheterization Laboratory

Mitchell J. Silver, Darren Traub, Amy J. Tracy, Charles F. Botti, Gary M. Ansel, MidWest Cardiology Research Foundation, Columbus, OH

Background: In order to understand the risk of carotid angiography performed by interventional cardiologists with peripheral vascular training, we undertook a retrospective study to determine the neurological complications in patients who underwent selective cerebral angiography.
Methods: Neurological complications were considered related to angiography when they occurred within 24 hours of the procedure. Hospital records were reviewed to determine any in-hospital neurological complications following carotid and cerebral angiography.
Results: A total of 483 consecutive patients underwent aortic arch and 4-vessel cerebral angiography. Almost 2/3 of patients were symptomatic. A total of 200/483 (41%) of patients also underwent coronary angiography at the same setting. There was one transient ischemic attack. There were no minor or major strokes, or death.
Conclusion: Experienced interventional cardiologists can perform diagnostic aortic arch and selective carotid and vertebral angiography in the cardiac catheterization laboratory with a very low complication rate. This will be important as cardiologists begin to manage more patients with peripheral vascular disease, and carotid stenting emerges as a viable option for high-risk patients in need of carotid revascularization.

1156-62 Economic Outcomes of Carotid Stenting Versus Endarterectomy for High Risk Patients: Preliminary Results From the SAPPHIRE Trial

David J. Cohen, Elizabeth Mahoney, Dan Greenberg, Amy Natjarian, Tara Lavelle, Patrick Walsh, Ronna H. Berezin, Jay Yadav, The SAPPHIRE Investigators, Harvard Clinical Research Institute, Boston, MA, Beth Israel Deaconess Medical Center, Boston, MA

Recently, stenting (S) has been shown to improve outcomes compared with endarterectomy (CEA) for high risk patients undergoing carotid revascularization. The true costs and cost-effectiveness of these alternative treatment strategies are unknown.
Methods: We prospectively measured medical resource utilization and cost for all 334 pts who were randomized to S or CEA in the SAPPHIRE trial. Procedural costs were based on measured resource utilization and current unit costs, while all other costs were estimated from hospital charges and hospital-specific cost-to-charge ratios.
Results: The primary endpoint of death, MI, or stroke at 30 days was reduced by 50% with S compared with CEA (4.8% vs. 9.6%, p=0.14). Compared with CEA, S was associated with shorter initial procedures and reduced post-procedure length of stay by ~1 day (see Table). As a result, S reduced hospital costs (excluding study devices) by more than $1200/pt and physician fees by ~$750/pt (p<0.001 for both). Nonetheless, when the costs of study devices were included, initial treatment costs were actually $813/pt higher with S. Full 1-year economic data and formal cost-effectiveness analysis will be available by 3/04.
Conclusions: Although S was associated with shorter procedures and lengths of stay than CEA, initial costs were increased modestly in this high risk population. The cost-effectiveness of S will thus depend on its ability to reduce follow-up medical care costs, to provide sustained reductions in major complications, or both.

Initial Hospital Resource Utilization and Costs

	Stent group (n=167)	Endarterectomy group (n=167)	Difference (95% CI)	P-value
Procedure duration (hours)	1.3 ± 0.6	3.0 ± 1.1	-1.6 (-1.8, -1.4)	<0.001
Length of stay (days)	1.9 ± 2.0	2.8 ± 3.6	-0.9 (-1.6, -0.3)	<0.001
Device costs	$2741 ± 710	$35 ± 307	$2706 (2583, 2829)	<0.001
Other hospital costs	$5949 ± 3475	$7175 ± 4801	-$1226 (-2155, -297)	<0.001
Physician costs	$2104 ± 294	$2850 ± 567	-$746 (-845, -646)	<0.001
Total Cost	**$10,794±3635**	**$9980 ± 4775**	**$813 (-128, 1755)**	**0.09**

1156-63 Inaccuracy of Doppler Ultrasonography for Assessing Restenosis After Internal Carotid Artery Stenting

Ravish Sachar, Herbert D. Aronow, Ivan P. Casserly, Mobeen Sheikh, Samir Kapadia, Deepak L. Bhatt, Christopher Bajzer, Jay S. Yadav, The Cleveland Clinic Foundation, Cleveland, OH

Background: Doppler ultrasonography is widely accepted as a means of non-invasively estimating internal carotid artery (ICA) stenosis. However, the utility of Doppler ultrasonography for assessing in-stent restenosis (ISR) after internal carotid stenting (CS) has not been well studied. We examined the relationship between Doppler ultrasound criteria and angiographic restenosis in patients after CS.
Methods: Two hundred and thirty-five patients who underwent CS at our institution and had a follow-up Doppler study done at a minimum of 5 months after the index procedure were studied. Patients with high-grade contralateral stenosis or occlusions were excluded. Twenty-four consecutive patients were identified who had ≥ 60% Doppler-defined ISR on follow-up exam (60-79%: PSV≥150 cm/sec, EDV<cm/sec; 80-99%: ≥150 cm/sec, EDV≥135 cm/sec). These patients subsequently underwent diagnostic carotid angiography. The PSV, EDV, and ICA/CCA ratio among patients who had true angiographic ISR were compared with those who did not.
Results: True ISR (≥50% by quantitative coronary angiography) was present in 8/24 patients (33.3%), while 16/24 patients (66.6%) did not have ISR by angiography. The median PSV (range: 152-427 cm/sec) and EDV (range: 34-200 cm/sec) for the entire cohort were 231 cm/sec and 65 cm/sec, respectively. The median PSV and EDV were significantly higher among patients with true angiographic ISR as compared to those without angiographic ISR (PSV: 350 cm/sec vs. 201 cm/sec, p=0.004; EDV: 139 cm/sec vs. 54 cm/sec, p=0.006). Furthermore, the median ICA/common carotid artery (CCA) ratio was significantly higher among patients with true angiographic restenosis as compared to those without (3.92 vs 1.62, p=0.009).
Conclusions: Among patients with carotid stents, current Doppler criteria for defining restenosis are not accurate. Modified Doppler criteria with higher thresholds for PSV and EDV, as well as the use of ICA/CCA ratios are more appropriate for assessing ISR after CS.

1156-64 Carotid Angioplasty and Stenting: Early and Late Follow-Up Results

Raffaella Manetti, Castriota Fausto, Enrico Ricci, Armando Liso, Kareem Oshoala, Alberto Cremonesi, Villa Maria Cecilia Hospital, Cotignola (RA), Italy

Purpose. Our objective was to evaluate immediate and long-term results of carotid angioplasty and stenting and the clinical impact of cerebral protection systems. **Materials/Methods.** From June 1997 to June 2003 a total of 674 patients (mean age 71 ±7,6) underwent carotid stenting for carotid stenosis.
Results. Primary technical success achieved in 672/674 (99,70%). Procedure failures were two. One for entrapment of Angioguard wire in the proximal edge of a Palmaz stent treated by surgical cut-down without complications and the second one due to a spiral dissection of internal carotid caused by Percusurge occlusive balloon. Twenty-eight (4,17%) patients had symptomatic complications : 1 (0,15%) death, 2 (0,30%) major stroke, 9 (1,34%) minor stroke, 8 (1,19%) intracranial hemorrhage, 7 (1,04%) TIA and 1 (0,15%) arterial wall perforation. . In hospital and 30-days complications in protected group (547 patients) was: 1 (0,18%)death, 2 (0,37%) major stroke, 6 (1,10%) minor stroke, 7 (1,28%) intracranial hemorrhage, 6 (1,10%) TIA and 1 (0,18%) arterial wall perforation. Embolic complications rate in protected group was 15 (2,75%). We used : Angioguard 236 (43,14%), Mednova Neuroshield 95 (17,37%), Trap-filter 67 (12,25%), Percusurge 26 (4,75%), MOMA 20 (3,66%), Accunet 15 (2,74%), Parodi System 7 (1,28%). Complications related to the use of embolic protection devices were: two (0,37%) dissection treated with an additional stent, one (0,18%) vessel occlusion by spiral dissection, one (0,18%) "trapped" guidewire.
Long-term outcome (range 3 months-72 months) was concluded in 510 patients. Patients free for major and minor neurologic events was 471 (92,35%). Complications: neurological death 4 (0,78%), major ipsi-lateral non-fatal stroke 2 (0,39%), minor ipsi-lateral non-fatal stroke 0 (0%), stent crush 1 (0,20%), stent migration 2 (0,39%), death (other causes) 17 (3,33%). Color-Doppler follow up examination showed 13 (2,55%) asymptomatic restenosis (⊃ 50%).
Conclusion. our results suggested that carotid angioplasty and stenting is a safe in term of early and long term results. Cerebral protection devices appears effective.

1156-65 Post-Carotid Artery Stent Hypotension and Optimal Pressor Use

Mohan R. Nandalur, Howard A. Cooper, Lowell Satler, Joseph Lindsay, John R. Laird, Washington Hospital Center, Washington, DC

Background: Hypotension is common following carotid artery stenting (CAS), and may be mediated by vagal stimulation and/or suppression of spinal sympathetic outflow. Both mixed α/β agonists dopamine (DA) and more selective α-agonists (norepinephrine (NE) and phenylephrine (PE)) have been used, but the most effective treatment of post-CAS hypotension is unknown. Methods: We analyzed data for consecutive patients requiring vasopressor treatment of post-CAS hypotension. Choice of vasopressor was made by the treating physician. Endpoints included infusion duration, coronary care unit (CCU) length of stay (LOS), TIA, new arrhythmia, cardioversion, angina, and any major adverse event. Results: Over 5 years, CAS stenting was performed in 438 patients. CCU admission, in atropine non-responders, for vasopressor treatment was required in 42 patients (9.6%): DA in 20 patients (48%), NE in 13 patients (31%), and PE in 9 patients (21%). Vasopressor infusion time was 31.8 ± 10.6 h for DA, compared with 23.8 ± 8.1 h for NE (p=0.052) and 22.2 ± 6.1 h for PE (p=0.028). CCU LOS was 46.5 ± 14.1 h for DA compared with 36.9 ± 9.1 h for the NE and PE groups combined (p=0.056). Adverse events are listed in the Table. Major adverse events were more common among patients receiv-